IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

ALLERGAN, INC. and DUKE UNIVERSITY, **Plaintiffs,** **v.** **APOTEX INC. and APOTEX CORP.,** **Defendants.**	**Case No. 1:10-CV-681**
ALLERGAN, INC. and DUKE UNIVERSITY, **Plaintiffs,** **v.** **SANDOZ, INC.,** **Defendant.**	**Case No. 1:11-CV-298**
ALLERGAN, INC. and DUKE UNIVERSITY **Plaintiffs,** **v.** **HI-TECH PHARMACAL CO., INC.,** **Defendant.**	**Case No. 1:11-CV-650**
ALLERGAN, INC. and DUKE UNIVERSITY, **Plaintiffs,**	**Case No. 1:12-CV-321**

v.

WATSON PHARMACEUTICALS, INC. N/K/A/ ACTAVIS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.,

Defendants.

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR PERMANENT INJUNCTION

I. INTRODUCTION

Permanent injunctions are routinely granted in Hatch-Waxman cases. Before filing their Motion, Plaintiffs asked each of the defendants to stipulate to such relief so as to avoid the pending motion practice. Plaintiffs received no response from Apotex, and only equivocal responses from the remaining defendants. Plaintiffs thus filed this Motion to ensure that the Defendants, as adjudicated infringers, would be personally bound by the Judgment in this case.

The due process and procedural considerations raised by Defendants provide no basis to deny injunctive relief. As for due process, Defendants could have deposed and can still depose the individuals who put forth declarations to support Plaintiffs' showing of irreparable harm. Plaintiffs still do not oppose such depositions or an evidentiary hearing on Plaintiffs' Motion for Permanent Injunction, should the Court consider one necessary. As for procedure, the Court's Judgment is not yet final because Plaintiffs'

request for injunctive relief remains outstanding and not all the relief prayed for in the Complaint has been ruled upon.[1] Moreover, the fact that the case is administratively "closed" does not divest the Court of jurisdiction. Accordingly, the Court may make additional findings on the requested injunctive relief, to the extent required by Federal Rules of Civil Procedure 52 and 65.

On the merits, Plaintiffs have demonstrated each element required for a permanent injunction to issue. Namely, Plaintiffs have demonstrated that both Allergan and Duke would suffer irreparable harm if any Defendant launched a generic copy of Latisse® before patent expiration, that monetary damages cannot adequately compensate for those injuries, and that the balance of hardships and considerations of the public interest weigh in favor of granting an injunction. Defendants do not substantively challenge Plaintiffs' showings, but instead claim that because it would be illegal to launch their products absent FDA approval, Plaintiffs cannot be harmed. But Congress has rejected this argument by specifically providing that injunctions may issue in Hatch-Waxman cases in addition to forbidding FDA from finally approving infringing ANDA products before patent expiration. 35 U.S.C. § 271(e)(4)(B). And, as evidenced by Apotex's conduct in the past, injunctive relief is necessary to personally bind Defendants from further infringement (as opposed to binding the FDA in relation to Defendants' ANDAs). In short, Defendants offer no good reason why a permanent injunction should not issue here.

[1]Plaintiffs currently seek dismissal of Defendants' appeal on the basis that the Judgment appealed from is not final, (*see* Ex. A), and Plaintiffs have previously argued to this Court that Defendants' appeal is premature on this basis. (*Allergan v. Apotex et al.*, Civil Action No. 12-cv-247 (Consolidated), Docket No. 85 at 12.)

Plaintiffs' Motion should be granted and a permanent injunction should issue against all Defendants.

II. ARGUMENT

A. Defendants' Procedurally Based Arguments Do Not Prevent the Court From Issuing an Injunction

Defendants' due process concerns could have been easily addressed by simply asking Plaintiffs to make Mr. Rhatigan and Mr. McCaughan available for deposition in the weeks after Plaintiffs filed their Motion. Plaintiffs do not oppose limited depositions pertaining to the declarations submitted in support of Plaintiffs' Motion for Permanent Injunction.[2]

But even so, Defendants' due process concerns do not prevent an injunction from issuing. Whether an evidentiary hearing is necessary to make any findings required to adjudicate a motion for permanent injunction is up to the Court. In instances where an evidentiary hearing would not alter the conclusion that a permanent injunction is warranted, no hearing is required. *See Lone Star Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc.*, 43. F.3d 922, 938 (4th Cir. 1995) (recognizing that "a court need not conduct an evidentiary hearing before issuing a permanent injunction if the affidavits and documentary evidence clearly establishes the plaintiff's right to the injunction such that a hearing would not have altered the result"); *United States v. McGee*, 714 F.2d 607, 613

[2] However, Mr. Rhatigan's declaration in support of Plaintiffs' Motion largely mirrors his trial testimony. Because Defendants cross examined Mr. Rhatigan on these issues at trial, Plaintiffs do not believe a further deposition of Mr. Rhatigan is warranted.

(6th Cir. 1983) (providing that an evidentiary hearing is "not necessary where no triable issues of fact are involved").

Here, it is clear from Defendants' opposition that they do not question the veracity of these declarants' statements, and thus have chosen not to depose Mr. Rhatigan or Mr. McCaughan. Defendants' entire argument that Plaintiffs will not and cannot suffer irreparable harm is *not* based on whether the harms Allergan and Duke identify are supported in fact, but rather on what Defendants allegedly cannot do under the law—sell a pharmaceutical product without final FDA approval. (Docket No. 219 at 6-7, 10-11.) But even that argument does not guarantee that Plaintiffs will not suffer irreparable harm. Indeed, Apotex has previously attempted to circumvent an infringement finding, demonstrating that they may not consider their hands tied by the Court's order under 35 U.S.C. § 271(e)(4)(A). *See Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831, 834-35 (N.D. Ill. 2006), *rev'd* 503 F.3d 1372 (Fed. Cir. 2007).

In short, Defendants' due process concerns are moot because neither depositions nor an evidentiary hearing would alter the conclusion that Allergan and Duke will suffer irreparable harm if any defendant launched a generic version of Latisse®. Nonetheless, Plaintiffs are available at the Court's convenience for an evidentiary hearing should the Court decide to hold one.

Defendants wrongly argue that entering a permanent injunction at this stage of the case—after a judgment has been entered—would violate procedural rules. (Docket No. 219 at 8.) However, prevailing parties routinely request, and courts grant, permanent

injunctions after trial and entry of non-final judgment. *See, e.g.*, *Universal Furniture Int'l v. Collezione Europa USA, Inc.*, No. 1:04-cv-977, 2007 WL 4262725, at *1-2 (M.D.N.C. Nov. 30, 2007) (entering permanent injunction after having previously issued initial findings of fact and conclusions of law); *see also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, No. 99-cv-870, 2006 WL 6925054, at *1 (D. Colo. Sept. 21, 2006) (referring to the Court's granting of a permanent injunction based on patentee's request after judgment was entered). That is certainly the norm in jury trials, where applications for permanent injunction are made after the jury returns a verdict. *See, e.g.*, *Mytee Prods., Inc. v. Harris Research, Inc.*, 439 Fed. App'x 882, 884, 887-88 (Fed. Cir. 2011) (affirming grant of permanent injunction after jury verdict); *ePlus, Inc. v. Lawson Software, Inc.*, 2011 WL 2119410 (E.D. Va. May 23, 2011) (addressing request for permanent injunction after jury verdict of infringement). There is no appreciable difference here, and courts routinely grant such requests after Hatch-Waxman trials. *See Research Foundation of State Univ. of N.Y. v. Mylan Pharms. Inc.*, 2012 WL 1901267 (D. Del. May 25, 2012) (granting permanent injunction close to one year after issuing post-trial opinion); *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc.*, 821 F. Supp. 2d 681 (D.N.J. 2011) (granting permanent injunction following Hatch-Waxman jury trial); *Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc.*, No. 04-1689, 2007 WL 869545 (D.N.J. Mar. 20, 2007) (entering permanent injunction upon application of plaintiff for entry of final judgment). In fact, a court faced with a similar procedural posture as here—having entered a judgment on liability but not as to all the requested

relief—concluded that its previously entered "final judgment" was not actually final, entertained a motion for permanent injunction, and issued an injunction. *AstraZeneca AB v. Mutual Pharm. Co.*, Civ. No. 00-4731, 2003 WL 22794868, at *1-3 (E.D. Pa. Nov. 12, 2003).

Defendants also argue, based on Rules 52 and 65, that the Court may not enter an injunction because it has made no findings of fact on the injunction issue. (Docket No. 219 at 7-9.) Plaintiffs acknowledge that the Court has not yet made all the findings required to issue an injunction, though the Court did find that Latisse® is a commercial success and that its "sales numbers have been impressive . . . and have increased in the years since the product was launched." (Docket No. 208 at 19.) But, as long as the Court makes findings of fact pursuant to Rules 52 and 65 that support an injunction, the Court may enter one, even at this stage. Because judgment is not yet final, and even though the cases are administratively labeled as "closed," the Court has jurisdiction to issue an injunction. *See Penn-America Ins. Co. v. Mapp*, 521 F.3d 290, (4th Cir. 2008) ("Put simply, an otherwise non-final order does not become final because the district court administratively closed the case after issuing the order."); *Pods, Inc. v. Porta Star, Inc.*, 484 F.3d 1359, 1365 (Fed. Cir. 2007) (finding notice of appeal premature where judgment addressed infringement and damages, but not plaintiff's request for permanent injunction); *see also* Ex. A.

Simply put, there is nothing procedurally incorrect with the timing of Plaintiffs' Motion, and the Court has authority to both hear it and issue an injunction if the Court finds one is warranted.

B. Plaintiffs Have Met Their Burden of Establishing the Four-Factor Injunction Test

On the merits, Defendants erroneously suggest that Plaintiffs cannot suffer irreparable harm because Defendants cannot launch their products absent FDA approval, which the Court has already delayed until patent expiration, at earliest. (Docket No. 219 at 10-11.) However, whether Defendants can legally do so does not tie their hands from engaging in other infringing conduct. Moreover, every generic company could feasibly make this same argument, yet injunctions regularly issue following a finding of infringement in a Hatch-Waxman case. (*See* Docket No. 212 at 5.) Congress has provided for this remedy, 35 U.S.C. § 271(e)(4)(B), and there is no reason why Defendants should not be subject to it given that Plaintiffs have demonstrated that each factor necessary to issue an injunction has been met.

An injunction is appropriate here because the relief the Court ordered under 35 U.S.C. § 271(e)(4)(A) delaying ANDA approval binds FDA, but not Defendants. As past conduct indicates, Defendants could undertake a number of activities that upset this Court's infringement determination if they are not enjoined. For example, Defendants could transfer their ANDAs to other entities or re-file their ANDAs under a different number, similar to a tactic Apotex has undertaken in using the "stalking horse" "Nu-Pharm" to file a nearly duplicative ANDA after its ANDA had been ruled infringing.

Abbott Labs., 544 F. Supp. 2d at 834-35. Here, Plaintiffs have attempted to craft an injunction that would prohibit Defendants from engaging in any of this improper conduct, similar to what another court has ordered in the past. (*See* Docket No. 211-1); *Sanofi-Aventis*, 821 F. Supp. 2d at 697 (enjoining defendants from submitting additional ANDAs that are "not colorably different" from defendants' original ANDAs, from sponsoring another company to submit an ANDA for a generic version of the brand product, and from manufacturing or selling the generic product to another for distribution within the United States).

Defendants incorrectly rely on *Alcon, Inc. v Teva Pharm. USA, Inc.*, No. 06-234-SLR, 2010 WL 3081327 (D. Del. Aug. 5, 2010) to argue that an injunction is not warranted. In *Alcon*, the branded company argued that they were entitled to an injunction based on a single irreparable harm argument that neither Allergan nor Duke make here—"that any deprivation of [Alcon's] right to exclude others constitutes irreparable harm to the monopoly granted by [its] patent." *Id.* at *2. Unlike in *Alcon*, both Allergan and Duke have demonstrated irreparable harm that will flow to them beyond their patent-based right to exclude. Indeed, as explained in Plaintiffs' opening brief, the harms Allergan and Duke identified are precisely the type of irreparable harms that cannot be compensated by monetary damages and that have led to the entry of permanent injunctions in myriad Hatch-Waxman cases. (Docket No. 211 at 5-12.)

Moreover, Defendants' suggestion that Plaintiffs' requested injunction would "unnecessarily restrain Defendants from using their ANDA products in a non-commercial

experimental manner" is incorrect. (Docket No. 219 at 13.) First, Plaintiff's proposed injunction only extends to the "***commercial*** manufacture use, offer to sell and/or sale" of the Defendants' ANDA products. (Docket No. 211-1 (emphasis added).) Second, the Hatch-Waxman Act expressly includes a "safe harbor" provision that provides that "[i]t shall ***not*** be an act of infringement" to make, use, offer to sell or sell a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs." 35 U.S.C. § 271(e)(1). Thus, certain non-commercial uses of Defendants' ANDA products may be protected by statute, which is precisely why Plaintiffs' proposed injunction is limited to commercial activities.

III. CONCLUSION

For the foregoing reasons, as well as those set forth in Plaintiffs' opening brief and any argument heard on the Motion at the April 5, 2013 hearing, Plaintiffs' respectfully request that the Court grant Plaintiffs' Motion for Permanent Injunction.

Respectfully submitted,

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/s/ Larry McDevitt

Larry McDevitt
N.C. State Bar No. 5032
David Wilkerson
N.C. State Bar No. 35742
THE VAN WINKLE LAW FIRM
11 North Market Street
Asheville, NC 28801
Telephone: (828) 258-2991
Facsimile: (828) 257-2767
E-mail: lmcdevitt@vwlawfirm.com
E-mail: dwilkerson@vwlawfirm.com

COUNSEL FOR PLAINTIFFS ALLERGAN, INC. AND DUKE UNIVERSITY

OF COUNSEL:

Jonathan E. Singer
Deanna J. Reichel
FISH & RICHARDSON P.C.
60 South Sixth St., #3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Email: singer@fr.com
Email: reichel@fr.com

Juanita R. Brooks
Roger A. Denning
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Email: brooks@fr.com
Email: denning@fr.com

Douglas E. McCann
Robert Oakes
A. Martina Tyreus Hufnal
Elizabeth M. Flanagan
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: 302-652-5070
Email: dmccann@fr.com
Email: oakes@fr.com
Email: hufnal@fr.com
Email: eflanagan@fr.com

Jeffrey T. Thomas
GIBSON DUNN & CRUTCHER
3161 Michelson Drive
Irvine, CA 92612
Telephone: 949-451-3800
Email: jtthomas@gibsondunn.com

CERTIFICATE OF SERVICE

I hereby certify that I have this day served the foregoing Plaintiffs' Reply Brief In Support of their Motion for Permanent Injunction on the following:

Darrell A. Fruth
dfruth@brookspierce.com
Jim W. Phillips, Jr.
jphillips@brookspierce.com
Eric M. David
edavid@brookspierce.com
BROOKS, PIERCE, MCLENDON,
HUMPHREY & LEONARD, L.L.P.
P.O. Box 26000
Greensboro, NC 27420

ATTORNEYS FOR DEFENDANT
APOTEX, INC. AND APOTEX CORP.

William A. Rakoczy
wrakoczy@rmmslegal.com
Paul J. Molino
paul@rmmslegal.com
Neil A. Benchell
nbenchell@rmmslegal.com
Andrew Alul
aalul@rmmslegal.com
Luke Shannon
lshannon@rmmslegal.com
Deanne M. Mazzochi
dmazzochi@rmmslegal.com
Harven V. DeShield
hdeshield@rmmslegal.com
Timothy Peterson
tpeteson@rmmslegal.com
Rakoczy Molino Mazzochi Siwik LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60654

ATTORNEYS FOR DEFENDANT
APOTEX, INC. AND APOTEX CORP.

F. Hill Allen
hallen@tharringtonsmith.com
THARRINGTON SMITH, L.L.P.
P.O. Box 1151
Raleigh, NC 27602-1151

ATTORNEYS FOR DEFENDANT
SANDOZ, INC.

Brandon C. Helms
bhelms@steptoe.com
Thomas Filarski
tfilarski@steptoe.com
Meredith Addy
maddy@steptoe.com
Thomas Rammer
trammer@steptoe.com
STEPTOE & JOHNSON LLP
115 S. LaSalle Street, Suite 3100
Chicago, IL 60603

ATTORNEYS FOR DEFENDANT
SANDOZ, INC.

Lyn K. Broom
klb@trslaw.com
Steven B. Fox
sbf@trslaw.com
TEAGUE ROTENSTREICH
STANALAND FOX
& HOLT, P.L.L.C.
101 S. Elm Street, Suite 350 (27401)
P.O. Box 1898
Greensboro, NC 27402-1898

ATTORNEYS FOR DEFENDANT HI-TECH PHARMACAL, INC.

Steven Roth
sroth@hitechpharm.com
HI-TECH PHARMACAL CO., INC.
369 Bayview Avenue
Amityville, NY 11701

Gary E. Hood
Mark Deming
Polsinelli Shughart
161 N. Clark Street, Suite 4200
Chicago, IL 60601
ghood@polsinelli.com
mdeming@polsinelli.com

ATTORNEYS FOR DEFENDANT WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.

Graham L.W. Day
Robyn H. Ast
Lauren W. Cohen
100 S. Fourth Street, Suite 1000
St. Louis, Missouri 63102
gday@polsinelli.com
rastgmoser@polsinelli.com
lcohen@polsinelli.com

ATTORNEYS FOR DEFENDANT WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.

Dated: March 28, 2013

/s/ Larry McDevitt
Larry McDevitt